K110273

JUN - 9 2011

510(k) SUMMARY

Date Prepared: June 9, 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. Submitter Information

Name:	Monaghan Medical Corporation
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Contact Person:	Cari J. Reil Regulatory Affairs Manager

2. Device Information

Device Trade Name:	***AeroVent Plus***™ Collapsible Holding Chamber
Common Name:	Aerosol Holding Chamber/Spacer
Classification Name:	Nebulizer (Direct Patient Interface)
Classification Number:	868.5630

3. Legally Marketed Predicate Devices

Device Trade Name:	***AeroVent***® Collapsible Holding Chamber
510(k) Number:	K894969
Manufacturer:	Monaghan Medical Corporation

Device Trade Name:	***AeroVent II***™ Collapsible Holding Chamber
510(k) Number:	K012939
Manufacturer:	Monaghan Medical Corporation

4. Device Description

The ***AeroVent Plus***™ Collapsible Holding Chamber (CHC) is a single patient use device used for the administration of MDI packaged drugs to mechanically ventilated patients without the need to compromise the integrity of the breathing circuit by having to open the circuit to administer the medication. The ***AeroVent Plus***™ CHC remains collapsed in the breathing circuit until such time that a treatment is required. The ***AeroVent Plus***™ CHC is then expanded while

remaining in the circuit and treatment is given. Upon completion of the treatment the ***AeroVent Plus***™ CHC is then once again collapsed in the circuit.

It is designed only for use in the inspiratory limb of a breathing circuit, to accommodate conventional pMDI canisters as well as most pMDI canisters with integrated dose counters (GSK type) while maintaining the counter function.

5. Intended Use

   The ***AeroVent Plus***™ CHC is a single patient use collapsible holding chamber that provides the means of delivering MDI packaged drugs into a ventilator breathing circuit. The intended environments for use include the home, hospitals and clinics.

6. Technological Characteristics

   The ***AeroVent Plus***™ CHC has the same function and intended use as the predicate devices, ***AeroVent***® CHC and ***Aerovent II***™ CHC. It is also approximately the same size.

   The ***AeroVent Plus***™ CHC allows for use of pMDI products with integrated dose counters, allowing the activation of the counter. The ***AeroVent***™ CHC or ***Aerovent II***™ CHC did not have this ability.

   The fittings on the ***AeroVent Plus***™ CHC have been standardized to comply with the ISO5356-1 standard as on the predicate of the ***Aerovent II***™ CHC.

7. Non-Clinical Test Summary

   The ***AeroVent Plus***™ CHC was tested to compare performance to the predicate device of ***AeroVent***® CHC, including:

   - MMAD – Mass Median Aerodynamic Diameter
   - Pressure Leak Testing
   - Environmental Testing
   - Mechanical Life Cycle

   In all cases the ***AeroVent Plus***™ CHC was comparable to the ***AeroVent*** ® CHC.

8. Clinical Performance Summary

   Clinical testing was not completed as it is not required to show substantial equivalence.

9. Conclusions

   The ***AeroVent Plus***™ CHC meets performance requirements and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Cari J. Reil
Regulatory Affairs Manager
Monaghan Medical Corporation
5 Latour Avenue, Suite 1600
Plattsburgh, New York 12901

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Re: K110273
Trade/Device Name: AeroVent Plus™ Collapsible Holding Chamber (CHC)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: May 26, 2011
Received: May 27, 2011

Dear Ms. Reil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K110273

Device Name: AeroVent Plus™ Collapsible Holding Chamber (CHC)

Indications for Use:

The AeroVent Plus™ CHC is a single patient use collapsible holding chamber that provides the means of delivering MDI packaged drugs into a ventilator breathing circuit. The intended environments for use include the home, hospitals and clinics.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110273

Prescription Use √ or Over-The-Counter Use ____

(Per 21 CFR 801.109)